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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,777	02/16/2001	Madhukar Matthew Thakur	THA01-C1003	5209

23973 7590 06/17/2005

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,777

Applicant(s)

THAKUR, MADHUKAR MATTHEW

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

S.O.D

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 3/14/05 wherein the specification was amended; claim 1 was amended; and claim 2 is canceled.

**Note:** Claims 1 and 3-9 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments/amendment filed 3/14/05 to the rejection of claims 1 and 3-9 made by the Examiner under 35 USC 102, 103, and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **102 Rejection**

The rejection is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

### **103 Rejection**

The rejection is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

### **112 First Paragraph Rejection**

The rejection of claims 1, 3, 4, and 7-9 under 35 USC 112, first paragraph, because the specification, while being enabling for the N4 configuration generated from the amino acid sequence Gly-(D)-Ala-Gly-Gly (page 6, of specification, lines 19-20), does not reasonably provide enablement for all N4 chelating moieties is MAINTAINED for reasons of record in the office action mailed 9/22/04 and those set forth below.

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Applicant asserts that independent claim 1 has been amended to specify that the radiolabeling moiety comprises a tetrapeptide moiety which complexes with a radionuclide in an N4 configuration and that based on the disclosure on page 7, line 17, a skilled artisan would be capable of preparing such tetrapeptides.

Applicant's arguments are non-persuasive because the specification and originally presented claims were directed to a radiolabeling moiety that was capable of complexing with a radionuclide. In the previous amendment, the variable M was directed to a radiolabeling moiety comprising a peptide chelating moiety that was capable of complexing with a radionuclide in an N4 configuration. Hence, since the phrase 'capable of complexing... N4 configuration' was not a positive claim limitation, the phrase was not given patentable weight. Now, Applicant has amended the claims to state that the variable M is a radiolabeling moiety comprising a tetrapeptide chelating moiety that complexes with a selected radionuclide in an N4 configuration. However, the amended claim still does not negate the fact that Applicant is enable for the N4 configuration generated from the amino acid sequence Gly-(D)-Ala-Gly-Gly (page 6, of specification, lines 19-20) which is set forth in the specification. There are no other references to a tetrapeptide in the specification that generates an N4 configuration when complexed. If Applicant is in disagreement with the Examiner, it is respectfully requested that Applicant point to a specific page/pages and line/lines wherein other tetrapeptide sequences that form N4 configurations are disclosed.

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**112 Second Paragraph Rejection**

The rejection is WITHDRAWN because Applicant has amended the claim to overcome the rejection.

**NEW GROUNDS OF REJECTION**

**New Matter Rejection**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to state that the variable 'M is a radiolabeling moiety comprising a tetrapeptide chelating moiety that complexes with a selected radionuclide in an N4 configuration'. The phrase is considered new matter because the specification and claims as originally filed were directed to the variable M defined as 'a radiolabeling moiety comprised of a chelating moiety capable of complexing with a selected radionuclide. Thus, the originally filed claims and the specification did not disclose any N4 tetrapeptide configuration other than that found generated from the amino acid sequence Gly-(D)-Ala-Gly-Gly (page 6, of specification, lines 19-20). Thus,

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it should be noted that the claims contain new matter because the scope is broader than the specifically disclosed species as originally set forth in the application.

#### COMMENTS/NOTES

5. It should be noted that claims 1 and 3-9 as now amended are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a composition having formulae (I) or (II) wherein M is a radiolabeling moiety comprising a tetrapeptide chelating moiety that complexes with a radionuclide in an N4 configuration. However, Applicant **MUST** address and overcome the 112 rejections above.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

June 9, 2005